

**REMARKS**

Applicant respectfully requests reconsideration. Claims 1-2, 4-5, 9, 11, 42-49 and 52-55 were previously pending in this application.

Applicant appreciates the indication by the Examiner that claims 4, 5, 9, 42 and 43 are allowable.

Applicant has amended claims 1, 2 and 4 without prejudice to pursuing claims directed to the subject matter of the claims prior to this amendment. Allowed claim 9 has been amended to remove one of the two peptides; this peptide, GLYDGREHS (SEQ ID NO:43), has been moved into new claim 56. Claim 11 has been canceled.

No new matter has been added.

**Request to Rejoin Non-elected Species**

Applicant respectfully requests rejoinder under 37 CFR 1.141 of the non-elected species within the elected claims; see, for example, page 2 of the Office Action mailed on November 29, 2006.

Applicant also requests rejoinder under 37 CFR 1.141 of the non-elected species of claims 10 and 51, drawn to a decapeptide having the amino acid sequence GLYDGMHELI (SEQ ID NO:44) or GLYDGREHSV (SEQ ID NO:45) [claim 10] or a decapeptide comprising the nonapeptide of claim 44 [claim 51]. The Examiner indicated that was a separate species on page 3 of the restriction requirement mailed on September 27, 2005. The Examiner indicated that claim 51 is drawn to a non-elected species; see page 2 of the Office Action mailed April 24, 2006.

**Rejections Under 35 U.S.C. § 112**

The Examiner rejected claims 1, 2, 11, 44-49 and 52-55 under 35 U.S.C. § 112, first paragraph, as not enabled by the specification. Applicant respectfully requests reconsideration.

Without conceding in any way the correctness or merit of the Examiner's assertion that the claims as previously pending are not enabled, Applicant has amended the claims to recite that the claimed polypeptides consist of the recited sequences.

The Examiner alleges on page 3 of the Office Action that the effect of the claimed polypeptides cannot be predicted due to "the unpredictable effect on MHC binding, and CTL recognition or activation of unknown flanking sequences...." Applicant respectfully notes that the claimed invention now is limited to polypeptides having known flanking residues, i.e., residues of SEQ ID NO:1, due to the recitation in the claims that the isolated polypeptides "an unbroken sequence of amino acids from SEQ ID NO:1".

The Examiner supports the allegations with several prior art references. First, these references are misquoted or misinterpreted. Second, even if the references teach what is alleged, the person of ordinary skill in the art would necessarily know of these teachings and therefore would be well versed in the possibility that flanking residues can affect MHC binding or CTL recognition characteristics.

Regarding the references quoted, a careful reading of the references shows that addition of flanking residues may affect presentation of peptides. The Bergmann reference, for example, shows that there are differences in activity, but the Examiner fails to mention that all of the peptides shown in Fig.1 work, as is shown in Fig.2. The Eisenlohr reference is quoted by the Examiner as teaching that addition of amino acids at the N- or C-terminus "abolishes the CTL recognition", citing the abstract. That is incorrect. Eisenlohr teaches that addition of two C-terminal amino acids "severely reduces" presentation of the peptides to CTLs; however, the

reference does not provide that such a change would “abolish” activity. Similarly, the addition of 10 amino acids is described in Eisenlohr as having “failed to increase antigenicity”, not to “abolish” activity. The Shastri reference is alleged to teach that presentation of peptides is “profoundly influenced” by specific added C-terminal flanking residues, which turn out to be anchor residues. Nevertheless, all peptides had activity; none of the N-terminal additions affected activity. In summary, the teachings of these references have been viewed in the most extreme way in order to support the allegation of the Examiner. A fair reading of the references does not support the allegations.

In addition, the prior art is assumed to be known by the person of ordinary skill in the art. Based on that knowledge, the skilled person would know that there may be effects of adding flanking amino acids. However, the prior art also amply demonstrates that the skilled person routinely tests such effects, using assays that are entirely standard and routine in the art. Therefore, *even if flanking residues have an effect*, the skilled person routinely determines such effects and thus would not have to engage in undue experimentation to make and use the claimed invention. Therefore it cannot be concluded that the claims are not enabled since nothing other than routine experimentation would be required.

For example, the skilled person would use one of the sequences taught in the application to complex with a major histocompatibility complex molecule type HLA-A2 or elicit an immune response from human lymphocytes. The skilled person then could add any desired flanking residue using standard procedures and test the resulting peptide(s) for activity using standard assays that are detailed in the application and further described in the prior art, such as the references cited by the Examiner. That activity cannot reasonably be viewed as “undue” experimentation.

The Examiner’s own citation of MPEP 2164.03 and the prior art supports Applicant’s view, since it is clear from the prior art citations that the person of ordinary skill in the art knew of the potential effects of flanking residues for many years. In contrast to the emphasized portion of MPEP 2164.03 on page 5 of the Office Action, the skilled person knows much about

the nature of the invention, again as evidenced by the prior art references cited by the Examiner. Predictability of an invention is not the touchstone of enablement – whether or not the claimed invention requires undue experimentation is. In this case, based only on the references cited by the Examiner, it is clear that the skilled person routinely investigated the effects of flanking residues, and therefore would not have to use undue experimentation.

Accordingly, withdrawal of this rejection is respectfully requested.

### **CONCLUSION**

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Dated: June 19, 2008

Respectfully submitted,

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